

Amendments to the Claims:

Please amend the claims as follows:

Claim 1 (Original): A method of preparing an elastomeric gasket material for use in a metered dose inhaler, said method comprising:

contacting an elastomeric gasket material to be used in a metered dose inhaler, which gasket material comprises one or more extractable compounds, with a solution comprising an organic solvent, wherein the solution is at a temperature of at least 40°C to extract at least a portion of at least one of the one or more extractable compounds from the elastomeric gasket material.

Claim 2 (Original): The method of claim 1, wherein the elastomeric gasket material comprises acrylonitrile butadiene rubber.

Claim 3 (Original): The method of claim 1, wherein at least one of the one or more extractable compounds is selected from the group consisting of nonylphenol isomers, 2,2'-methylenebis(6-tertbutyl-4-methylphenol), 2,2,4,6,6-pentamethylhept-3-ene, 3'-oxybispropanitrile, oleic acid, palmitic acid, and stearic acid.

Claim 4 (Original): The method of claim 1, wherein at least one of the one or more extractable compounds has a vapor pressure greater than 45 torr (6000 Pa) at a temperature of 20°C.

Claim 5 (Original): The method of claim 1, wherein the solution comprises a lower alcohol.

Claim 6 (Original): The method of claim 5, wherein the solution further comprises an acid.

Claim 7 (Original): The method of claim 6, wherein the solution has a pH less than 5.5.

Claim 8 (Original): The method of claim 6, wherein the solution has a pH between 2.5 and 6.0.

Claim 9 (Original): The method of claim 5, wherein the lower alcohol is ethanol or isopropanol.

Claim 10 (Original): The method of claim 5, wherein the solution consists essentially of ethanol.

Claim 11 (Original): The method of claim 1, wherein the elastomeric gasket material is contacted with the solution for at least 1 hour.

Claim 12 (Original): The method of claim 1, wherein the elastomeric gasket material is contacted with the solution at a temperature of at least 60°C.

Claim 13 (Original): The method of claim 1, wherein the elastomeric gasket material is contacted with the solution under reflux conditions for the solution.

Claim 14 (Original): The method of claim 1, wherein the elastomeric gasket material is contacted with the solution in the presence of ultrasonic energy.

Claim 15 (Original): The method of claim 1, wherein the elastomeric gasket material is contacted with the solution under conditions sufficient to extract at least 20 percent of at least one of the one or more extractable compounds.

Claim 16 (Original): The method of claim 1, wherein the elastomeric gasket material is contacted with the solution under conditions sufficient to extract at least 40 percent of at least one of the one or more extractable compounds.

Claim 17 (Original): The method of claim 1, further comprising agitating the elastomeric gasket material.

Claim 18 (Original): The method of claim 17, wherein the agitating of the elastomeric gasket material is performed subsequent to the contacting of the elastomeric gasket material with the solution.

Claim 19 (Original): The method of claim 18, further comprising contacting the elastomeric gasket material with the solution subsequent to the agitating of the elastomeric gasket material.

Claim 20 (Currently amended): A method of making an elastomeric sealing gasket for use in a metered dose inhaler, said method comprising:

contacting an elastomeric gasket material configured to be used in a metered dose inhaler, which gasket material comprises one or more extractable compounds, with a solution comprising an organic solvent, wherein the solution is at a temperature of at least 40°C, under conditions sufficient to extract a portion of at least one of the one or more extractable compounds from the elastomeric gasket material; and
forming a sealing gasket from the elastomeric gasket material.

Claim 21 (Original): The method of claim 20, wherein the contacting of the elastomeric gasket material occurs after the forming of the sealing gasket.

Claim 22 (Original): The method of claim 20, wherein the forming of the sealing gasket comprises cutting the sealing gasket material to provide the sealing gasket.

Claim 23 (Original): The method of claim 21, wherein the sealing gasket material is in the shape of a sheet of sealing gasket material.

Claim 24 (Original): The method of claim 21, wherein the sealing gasket material has a thickness between 0.5 and 2 mm.

Claim 25 (Currently amended): A method of making an elastomeric MDI sealing gasket comprising:

contacting a base polymer starting material that comprises one or more extractable compounds with a solution comprising an organic solvent, wherein the solution is at a temperature of at least 40°C, under conditions sufficient to extract at least a portion of at least one of the one or more extractable compounds from the base polymer starting material to provide a treated raw polymer material;
producing elastomer from the treated raw polymer material; and
forming an MDI gasket from the elastomer.

Claim 26 (Cancelled)

Claim 27 (Currently amended): A sealing gasket for use in an MDI which sealing gasket has been treated by a method as claimed in ~~any one of claims claim 1 to 19 or~~ has been made according to a method as claimed in any one of claims 20 to 26.

Claim 28 (Original): A sealing gasket for use in an MDI comprising:

an elastomeric gasket material; and
between 0.04 and 0.17% oleic acid.

Claim 29 (Original): A sealing gasket as claimed in claim 28, further comprising between 0.05 and 0.35 palmitic acid.

Claim 30 (Currently amended): A sealing gasket as claimed in claim 28 ~~[[or 29]]~~, further comprising between 0.03 and 0.12 elaidic acid.

Claim 31 (Currently amended): A sealing gasket as claimed in ~~any of claims claim 28 through 30~~, further comprising between 0.06 and 0.12 stearic acid.

Claim 32 (Original): A method of manufacturing an MDI comprising providing an MDI sealing gasket as claimed in claim 27, providing the other MDI components and a pharmaceutical aerosol formulation and assembling the MDI.

Claim 33 (Original): A method as claimed in claim 32 wherein the pharmaceutical aerosol formulation comprises salmeterol xinafoate, fluticasone propionate or a combination of those with each other or with one or more further medicaments.

Claim 34 (Currently amended): A metering valve suitable for metering a drug suspension comprising a medicament and a propellant, which metering valve comprises a valve body, a metering chamber, a valve stem and one or more sealing gaskets as claimed in ~~any one of claims~~ claim 27 ~~through 31~~.

Claim 35 (Currently amended): A container comprising a canister sealed with a metering valve and a sealing gasket, which canister contains a pharmaceutical aerosol formulation comprising a propellant and a medicament, wherein the sealing gasket is one as claimed in ~~any one of claims~~ claim 27 ~~through 31~~.

Claim 36 (Original): A container as claimed in claim 35, wherein the pharmaceutical aerosol formulation comprises between a lower limit of 0.7 and an upper limit of 7.0 μg of palmitic acid after storage at 40°C for 2 weeks.

Claim 37 (Currently amended): A container as claimed in claim 35 ~~[[or 36]]~~, wherein the pharmaceutical aerosol formulation comprises between a lower limit of 0.7 and an upper limit of 7.0 μg of oleic acid after storage at 40°C for 2 weeks.

Claim 38 (Currently amended): A container as claimed in ~~any one of claims~~ claim 35 ~~through 37~~, wherein the pharmaceutical aerosol formulation comprises between a lower limit of 0.0 and an upper limit of 0.4 μg of elaidic acid after storage at 40°C for 2 weeks.

Claim 39 (Currently amended): A container as claimed in ~~any one of claims claim~~ 35 ~~through 38~~, wherein the pharmaceutical aerosol formulation comprises between a lower limit of 0.0 and an upper limit of 4.0 μ g of stearic acid after storage at 40°C for 2 weeks.

Claim 40 (Currently amended): A metered dose inhaler comprising a canister in communication with a metering valve suitable for metering a drug suspension comprising a medicament and a liquid propellant, wherein the metering valve and the canister are sealed with a sealing gasket as claimed in ~~any one of claims claim~~ 27 ~~through 31~~.

Claim 41 (Currently amended): A drug product comprising a canister containing a drug suspension comprising a propellant and a medicament in communication with a metering valve suitable for metering a drug suspension comprising a medicament and a liquid propellant, wherein the metering valve and the canister are sealed with one or more sealing gaskets as claimed in ~~any one of claims claim~~ 27 ~~through 31~~.

Claim 42 (Cancelled)

Claim 43 (Original): A method of treating asthma or COPD in a patient which comprises use by the patient of a metered dose inhaler as claimed in claim 32.

Claim 44 (Currently amended): A method of prolonging the shelf-life of a metered dose inhaler drug product comprising assembling the metered dose inhaler from parts including one or more sealing gaskets as claimed in ~~any one of claims claim~~ 27 ~~through 31~~.

Claims 45-48 (Cancelled)